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Bulletin & Update

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

*The Committee for the Protection of Human Subjects (CPHS) will periodically release issues of the **Bulletin & Update** to inform researchers and others regarding important changes in CPHS procedures as well as State and National issues of importance for human subject protection in research. Copies of the **Bulletin & Update** will be distributed via e-mail to researchers as well as posted on the CPHS web site (www.oshpd.ca.gov/cphs).*

This edition of the Bulletin and Update presents guidance for researchers on topics concerning the handling of data. Use of this guidance by researchers is highly recommended, but not required, by CPHS. Researchers may seek approval from CPHS for alternative approaches.

Guidance for Using Small Numbers or Small Cells

Definition of a small cell or a small number

- A cell is the intersection of a row and a column in a table, a spreadsheet, or in any matrix of numbers. For example, a table with four rows and three columns has twelve cells.
- The CPHS considers a cell small when it contains 1 to 15 research subjects.
- Some projects do not report data as tables but still might describe the characteristics of small numbers of subjects. Whenever a project describes 1 to 15 subjects it is important to be especially careful that the identities of all subjects are protected from possible disclosure.

Why small numbers or small cells are potential problems

A small number of subjects in a descriptive report or small cells in a table could potentially lead to the unintended identification of a research subject's identity. With a small study population, or with a small subset of a larger population, researchers should be careful about possibly identifying subjects. For example, research subjects in a rural community might be easily identified because their community has only one or two instances of a particular disease. Similarly, multiple tables describing an urban community might allow for the deduction of a subject's identity through a process of subtraction involving cells if the numbers in them are sufficiently small.

Suggested methods for dealing with small cells or small numbers

- Eliminate tables with small cells or data descriptions with small numbers.
- Within a table, combine (collapse) the row (or column) containing a small cell with another row (or column) to increase cell size.
- Combine the different time periods, such as fiscal years, represented by two or more tables (or descriptions) into a single table (or description) to increase cell size (or number size).

continued on next page

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- Suppress a small cell with a non-numeric symbol that hides the number of subjects, (for example {sc}). To prevent the identification of a small cell through subtraction, the suppression symbol should appear at least twice in the row and column of each of its intersections, as in the following example:

	> 65 yrs	18-64 yrs	< 18 yrs	TOTAL
agree	{sc}	30	{sc}	60
neutral	{sc}	60	{sc}	150
disagree	70	90	80	240
undecided	0	0	0	0
TOTAL	120	180	150	450

- Use of these suggested methods is recommended but not required by the CPHS. Researchers may request approval from CPHS for using alternative methods to protect subject identity when using small cells or small numbers.

Guidance for New Projects Using OSHPD Data

The second topic addresses the need for consistency between the applications submitted by researchers for non-public patient-level data to the Health Information Resource Center (HIRC) of the Office of Statewide Health Planning and Development (OSHPD) and the protocols submitted to CPHS for this data. Because of discrepancies between the two applications, HIRC and CPHS have developed a suggested process to reduce the inconsistencies and to assist the researchers in more accurately describing data needed in the CPHS protocol. The process includes the following steps:

- The researcher requesting non-public patient-level data from HIRC first completes and submits the CPHS protocol, without the Curriculum Vitae or other CPHS attachments, and the HIRC paperwork to HIRC for a preliminary review. Researchers should contact OSHPD HIRC staff, Louise Hand @ 916-322-7172 or lhand@oshpd.ca.gov, to arrange this review.
- HIRC staff and the OSHPD Internal Review Committee (IRC) review the HIRC application and the portions of the CPHS protocol that pertain to the data issues of concern to HIRC.
- HIRC staff coordinates with researchers to resolve any discrepancies.
- HIRC provides the researcher with a letter granting preliminary approval for release of requested data.
- The researcher then submits the revised protocol to CPHS, along with a copy of the HIRC approval letter.
- CPHS reviews the protocol and, if it approves the project, sends the researcher an approval letter.
- The researcher submits the approved protocol and CPHS approval letter to HIRC.
- The HIRC IRC formally reviews the project and the Chief Information Officer makes the final decision on release of data.